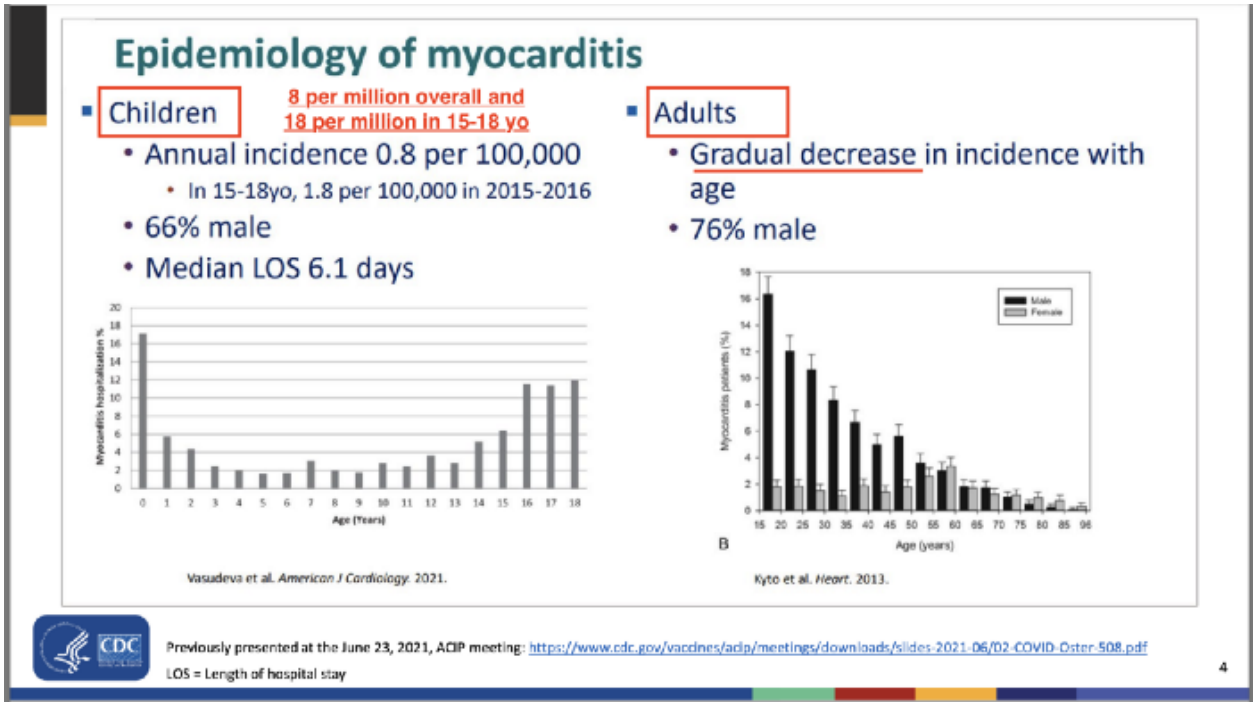
Myocarditis after COVID-19 Vaccination

The Stupefying and Humbling True Magnitude

Image from Recognition and Initial Management of Fulminant Myocarditis

BACKGROUND

Myocarditis (inflammation of the heart muscle) can cause serious life-threatening complications (discussed in greater detail in previous publication). Numerous causes of myocarditis have been established, the leading cause being viruses. As noted in ACIP June 23 Update on Myocarditis following mRNA COVID-19 Vaccination, the background rate in the general population (before COVID pandemic) was about 8 cases per million in the pediatric population (0–18 years old), and 18 per million in 15–18 year-old adolescents. For adults, the rate gradually decreases with age. For both children and adults, the incidence is much higher in males than in females.


Epidemiology of myocarditis
Children
8 per million overall and
18 per million in 15-18 yo
Annual incidence 0.8 per 100,000
In 15-18yo, 1.8 per 100,000 in 2015-2016
66% male
Median LOS 6.1 days
Adults
Gradual decrease in incidence with age
76% male
Age (Years)
Vasudeva et al. American J Cardiology. 2021.
Age (years)
Kyto et al. Heart. 2013.
Previously presented at the June 23, 2021, ACIP meeting: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf
LOS = Length of hospital stay
4

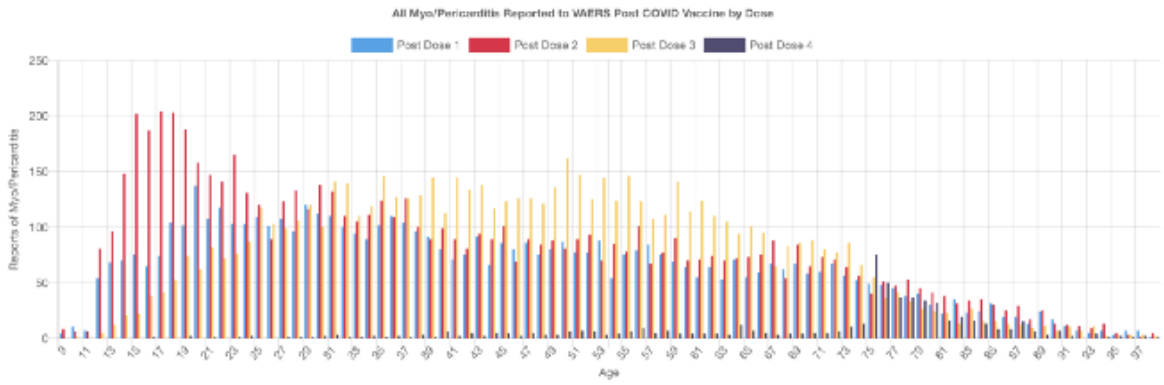
[Update on Myocarditis Following mRNA COVID-19 Vaccination]

During the past 2.5 years of the COVID-19 pandemic, both [SARS-CoV2 infection] and [COVID-19 mRNA vaccines] have been associated with myocarditis. Knowing the spike protein's affinity to ACE2 receptors in the heart and spike protein's [injury to cardiomyocytes] (cells of the heart), the association of myocarditis with SARS-CoV2 virus or spike protein-based mRNA vaccination was not unexpected. Initial [reports from Israel] of myocarditis after vaccination surfaced in April 2021. Public Health officials in US have continued to insist that myocarditis after SARS-CoV2 infection also occurs. They emphasize [CDC's analysis] which erroneously concludes risk of myocarditis after SARS-CoV2 infection is greater than after mRNA COVID-19 vaccination. Currently, *over 50,000 cases* of myocarditis, pericarditis, or both are reported in VAERS. As the discussion below will demonstrate, the actual number of myocarditis cases may be 3–4 times greater than reported in VAERS and the rate after vaccination is greater than after COVID-19 infection.

VAERS COVID Vaccine
Myo/Pericarditis Reports

Through July 1, 2022

50k and counting



[OpenVaers]

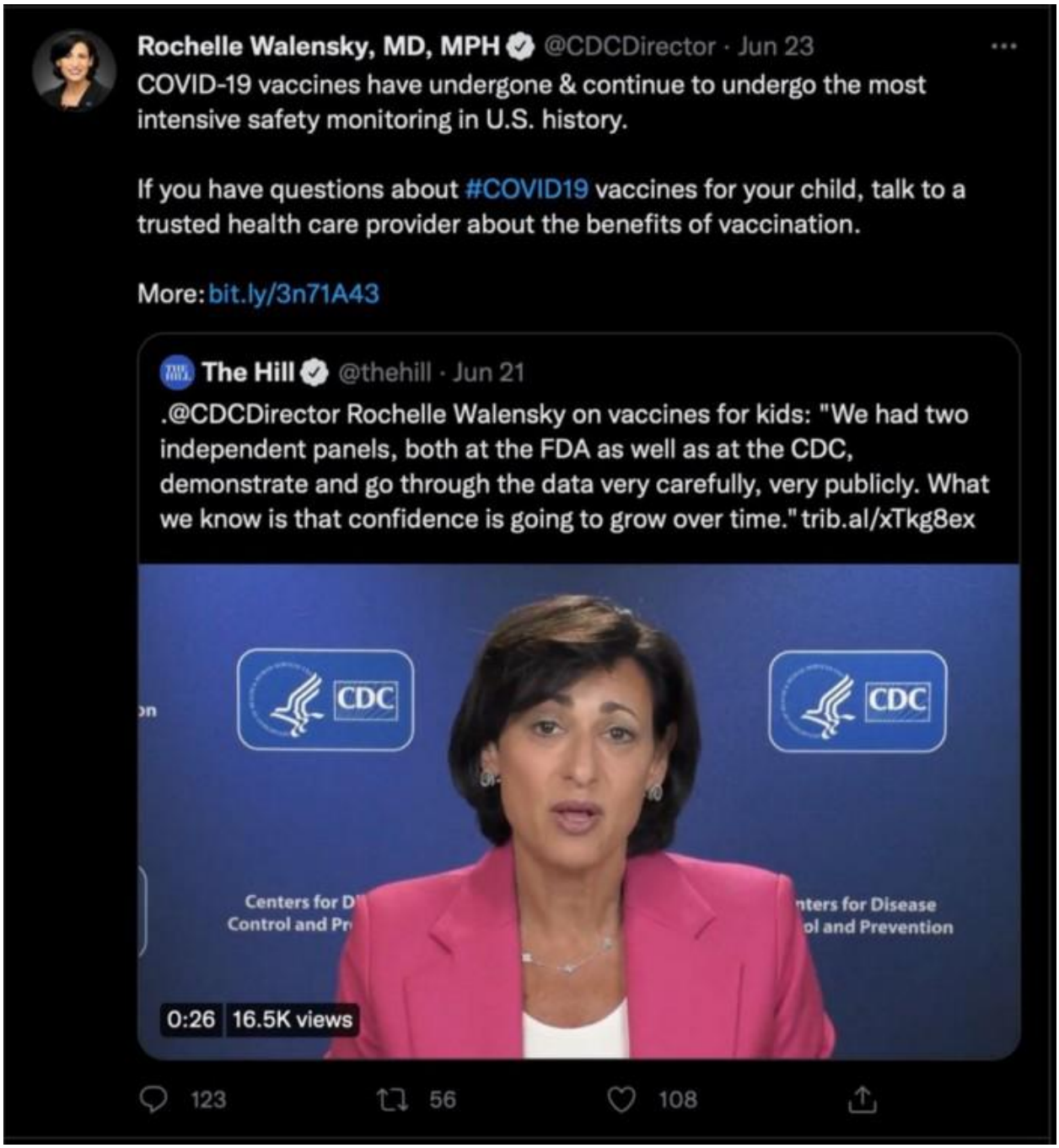
FDA granted EUA for mRNA vaccination against COVID-19 for those 6 months to 5 years old this past month. [CDC now recommends] vaccination against COVID-19 for everyone 6 months and older, regardless of risk stratification or prior infection with SARS-CoV2. Infection with SARS-CoV2 has been repeatedly proven to confer sustained and durable protection against COVID+ hospitalization and deaths.

CDC
@CDCgov
#COVID19 Vaccine Update: Everyone 6 months and older should get vaccinated against COVID-19. Getting vaccinated can help protect you from severe disease, hospitalization, and death from COVID-19.
Learn more: bit.ly/3CJme0v
!
COVID-19 VACCINE UPDATE
Who should get vaccinated against COVID-19?
Everyone ages 6 months and older
CDC
ALT
cdc.gov/coronavirus
9:20 AM · Jun 19, 2022 · Sprout Social

https://twitter.com/CDCgov/status/1538557223424638979?s=20&t=46O4qjOVY-CyvZ3EYJ8Qzw

Using data mostly from passive surveillance data in VAERS (supplemented with data from Vaccine Safety Datalink, or VSD), CDC continues to emphatically assert that the COVID-19 vaccines are “safe and effective”. Repeated studies have shown rapidly decreasing vaccine efficacy (VE) in children and adolescents during the first few months after completing vaccination (here I discuss two recent studies demonstrating the decreasing VE in pediatric population). Adults also need repeated boosters due to rapidly diminishing protection over time. Despite the proven dramatic drop in VE over time, all of CDC’s risk benefit analysis (i.e, number needed to vaccinate to prevent one COVID+ hospitalization) are based on the orginal short term

high VE. CDC extrapolates the original high VE as if it will be sustained, despite numerous studies demonstrating reduced VE within a few months. The decreasing VE then then begs the question if the benefits outweigh the risks in healthy children and young adults given the known increased, risk of myocarditis.


Rochelle Walensky, MD, MPH @CDCDirector · Jun 23
COVID-19 vaccines have undergone & continue to undergo the most intensive safety monitoring in U.S. history.
If you have questions about #COVID19 vaccines for your child, talk to a trusted health care provider about the benefits of vaccination.
More: bit.ly/3n71A43
The Hill @thehill · Jun 21
.@CDCDirector Rochelle Walensky on vaccines for kids: "We had two independent panels, both at the FDA as well as at the CDC, demonstrate and go through the data very carefully, very publicly. What we know is that confidence is going to grow over time." trib.al/xTkg8ex
CDC
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0:26 16.5K views
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https://twitter.com/CDCDirector/status/1540021330589925378?s=20&t=NztKJ0Pe_a4-imcCBEyWuw

CDC ANALYSIS OF VACCINE ASSOCIATED MYOCARDITIS DEEPLY FLAWED

CDC's analysis of Vaccine Associated Myocarditis (VAM) has been and repeatedly fatally flawed. CDC continues to use VAERS data alone in most of their meeting presentations despite prior studies demonstrating that VAERS underestimates the risk of myocarditis after vaccination by 3–4 times (when compared to insurance claims data or electronic health records (EHR) databases from hospitals. In another study comparing two methodologies even found that the CDC's method of VSD analysis under estimated the risk of VAM. The FDA Summary Basis of Regulatory Action noted that the rate of VAM in VAERS was 40 cases per million doses, "while an FDA meta-analysis of four healthcare claims databases in CBER's Biologics Effectiveness and Safety System estimated a rate of 148 cases per 1 million males 18 to 25 years of age vaccinated with the 2-dose primary series" (*3.7 times greater than the rate determined from VAERS alone*). For the cases of myocarditis after SARS-CoV2 infection, CDC uses officially confirmed PCR+ 'cases' (for the denominator), even though their own seroprevalence data demonstrates that far more people have been infected than officially conformed PCR+ 'cases'. For example, seroprevalence data as of Feb 21, 2022 reveal 75% (about 54 million) of all children have been infected compared to 12 million officially confirmed PCR+ 'cases' (i.e., the actual number of kids infected is 4.5 times greater than PCR+ 'cases'). Therefore, calculating the risk of myocarditis after SARS-CoV2 infection, the rate noted by CDC would need to be reduced by approximately 4.5 times for pediatric population. Thus far, CDC has not adjusted its COVID-19 morbidity and mortality data accordingly. CDC's perfunctory refrain that most cases of VAM were "generally mild" based upon follow-up on VAM reports in VAERS will be critiqued separately (forthcoming) but has been briefly reviewed at the end of my previous publication.

STUDIES DEMONSTRATING THE TRUE INCIDENCE OF MYOCARDITIS MUCH HIGHER THAN CDC ESTIMATES

nature COMMUNICATIONS

ARTICLE

https://doi.org/10.1038/s41467-022-31401-5 OPEN

Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines

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https://www.nature.com/articles/s41467-022-31401-5

In this peer reviewed French study, the authors evaluated national hospital discharge data for myocarditis after mRNA COVID-19 vaccination compared to unvaccinated controls. Compared to CDC's reliance on VAERS this French study performs a more comprehensive analysis. The analysis indicates the risk of myocarditis after mRNA vaccination was *8 times greater* than unvaccinated controls for BNT162b2 (Pfizer-BioNTech) and and *30 times greater* than unvaccinated controls for mRNA-1273 (Moderna). By comparison history of SARS-CoV2 infection yielded a *9 times greater* risk of myocarditis than controls.

Table 2 Association between myocarditis and pericarditis and exposure to mRNA vaccines within 1 to 7 days and 8 to 21 days.

		Myocarditis				Pericarditis			
		Cases	Controls	OR (95% CI)[a]	aOR (95% CI)[b]	Cases	Controls	OR (95% CI)[a]	aOR (95% CI)[b]
Unexposed	Days[c]	1078	13342	Reference	Reference	1269	13398	Reference	Reference
BNT162b2									
Dose 1	1-7	51	370	1.7 (1.3-2.4)	1.8 (1.3-2.5)	43	398	1.1 (0.83-1.6)	1.3 (0.92-1.8)
	8-21	71	855	1.1 (0.86-1.4)	1.2 (0.93-1.6)	72	824	0.94 (0.73-1.2)	0.93 (0.72-1.2)
Dose 2	1-7	211	439	6.9 (5.7-8.4)	8.1 (6.7-9.9)	93	374	2.7 (2.2-3.5)	2.9 (2.3-3.8)
	8-21	72	816	1.2 (0.95-1.6)	1.3 (0.98-1.7)	80	765	1.2 (0.91-1.5)	1.3 (0.98-1.6)
mRNA-1273									
Dose 1	1-7	9	48	2.4 (1.2-5)	3 (1.4-6.2)	8	78	1.1 (0.52-2.2)	1.2 (0.56-2.4)
	8-21	10	109	1.2 (0.63-2.3)	1.1 (0.55-2.3)	9	146	0.65 (0.33-1.3)	0.73 (0.37-1.4)
Dose 2	1-7	106	51	27 (19-39)	30 (21-43)	26	54	5.3 (3.3-8.4)	5.5 (3.3-9)
	8-21	4	89	0.68 (0.25-1.9)	0.59 (0.19-1.9)	11	89	1.4 (0.72-2.5)	1.5 (0.76-2.9)
History of myocarditis or pericarditis[d]									
No		1486	16111	Reference	Reference	1440	16122	Reference	Reference
Yes		126	9	140 (71-280)	160 (83-330)	173	8	250 (120-520)	250 (120-540)
History of SARS-CoV-2 infection[e]									
No		1548	16013	Reference	Reference	1571	16020	Reference	Reference
Yes		64	107	6.3 (4.6-8.6)	9 (6.4-13)	42	110	3.9 (2.7-5.7)	4 (2.7-5.9)
Deprivation Index[f]									
Most deprived		986	9567	Reference	Reference	1049	10080	Reference	Reference
Least deprived		626	6553	0.9 (0.8-1)	0.88 (0.77-1)	564	6050	0.87 (0.77-0.98)	0.87 (0.76-0.99)

[a]Odds-ratio (95% confidence interval) were obtained from univariable conditional logistic regression, adjusting for matching variables (sex, age and department of residence).
[b]Adjusted odds-ratio (95% confidence interval) were obtained from multivariable conditional logistic regression, adjusting for all covariates and matching variables.
[c]Period of vaccine receipt relative to index date.
[d]Defined as an hospitalization with the respective condition within past 5 years.
[e]Either a positive RT-PCR or antigenic test for SARS-CoV-2, or hospitalization for COVID-19, within 30 days prior to index date.
[f]Least deprived refers to the grouping of 1st and 2nd quintiles, and most deprived to the grouping of 3d to 5th quintiles of the deprivation index.

[Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines]

Subgroup analysis by age and sex (supplementary appendix) found the risk of myocarditis in 18–24 year-old males to be 13 times and *44 times greater than unvaccinated controls* for BNT162b2 and mRNA-1273, respectively (adjusting for prior myocarditis within past 5 years, deprivation index, and history of SARS-CoV2 infection within the past month). While much of the attention is given to adolescents and young adults (less than 30 years old), this study found the increased risk persisted in middle aged adult males also. For 30–39 year-olds, there was a *45 times greater* risk after mRNA-1273 compared to unvaccinated controls, while 40- 50 year-olds had *21 times greater* risk after mRNA-1273 compared to unvaccinated controls BNT126b2 was also associated with increased risk, but not to the same degree (see Table S2 below).

Table S2. Association between myocarditis and exposure to mRNA vaccines within 7 days, according to sex and age group (as illustrated in Figure 1).

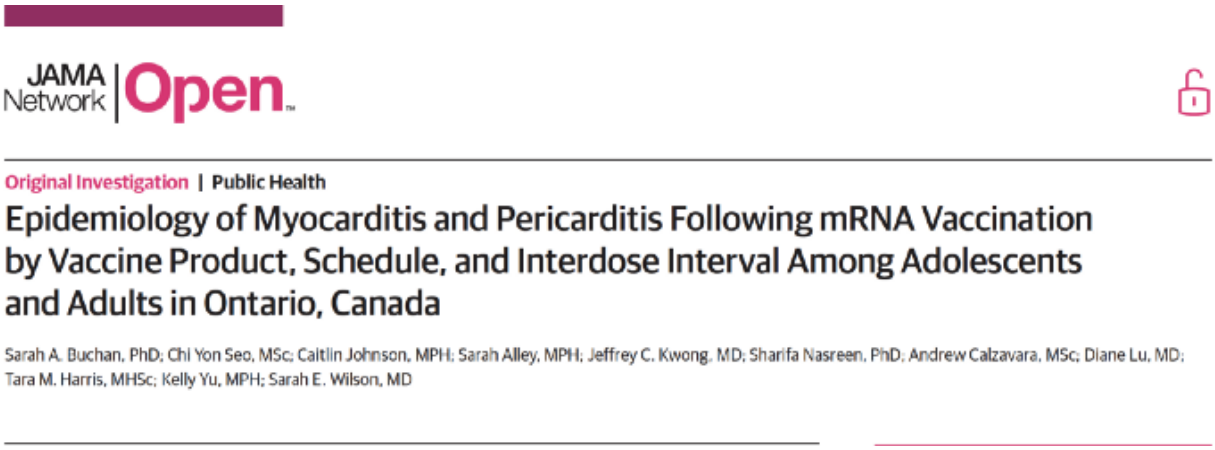
			Male				Female			
Age	Exposure	Dose	Cases	Controls	OR (95% CI)[a]	aOR (95% CI)[b]	Cases	Controls	OR (95% CI)[a]	aOR (95% CI)[b]
12-17	Unexposed		92	1,119	Reference	Reference	22	248	Reference	Reference
	BNT162b2	1	3	49	0.71 (0.21-2.3)	0.86 (0.26-2.9)	1	2	6.1 (0.54-70)	8.5 (0.69-110)
		2	30	37	14 (7.4-26)	18 (9-35)	4	13	4.7 (1.1-20)	7.1 (1.5-33)
	mRNA-1273	1	0	1	-	-	0	0	-	-
		2	2	0	-	-	0	0	-	-
18-24	Unexposed		290	3,940	Reference	Reference	67	863	Reference	Reference
	BNT162b2	1	16	113	2.2 (1.3-3.8)	2.1 (1.2-3.7)	2	29	0.9 (0.2-4)	0.9 (0.2-4.1)
		2	88	130	12 (8.5-17)	13 (9.2-19)	12	25	7.8 (3.5-18)	9.6 (4.3-22)
	mRNA-1273	1	2	12	2.6 (0.56-13)	2.6 (0.56-13)	1	2	6.5 (0.57-76)	15 (1.1-200)
		2	38	12	46 (23-91)	44 (22-88)	11	4	33 (10-100)	41 (12-140)
25-29	Unexposed		138	1,743	Reference	Reference	30	348	Reference	Reference
	BNT162b2	1	8	32	3.3 (1.5-7.4)	4 (1.7-9.3)	0	12	-	-
		2	28	61	6.3 (3.8-10)	7.1 (4.2-12)	4	7	7.5 (1.8-31)	10 (2.1-47)
	mRNA-1273	1	1	5	2.4 (0.27-20)	3.4 (0.37-31)	0	2	-	-
		2	17	13	20 (9-45)	19 (8.3-43)	2	1	20 (1.8-220)	23 (2.1-270)
30-39	Unexposed		178	2,307	Reference	Reference	70	735	Reference	Reference
	BNT162b2	1	12	44	3.6 (1.9-7)	3.7 (1.9-7.4)	4	21	2 (0.66-5.9)	2.2 (0.64-7.4)
		2	25	72	4.8 (2.9-8)	5.7 (3.4-9.5)	5	19	2.7 (1-7.5)	4 (1.4-11)
	mRNA-1273	1	1	11	1.4 (0.17-11)	1.5 (0.19-12)	2	4	5.2 (0.94-28)	8.8 (1.5-52)
		2	24	7	41 (17-95)	45 (19-110)	1	4	2.6 (0.29-24)	1.4 (0.11-18)
40-50	Unexposed		132	1,471	Reference	Reference	59	568	Reference	Reference
	BNT162b2	1	4	55	0.75 (0.27-2.1)	0.94 (0.33-2.7)	1	13	0.7 (0.089-5.5)	0.88 (0.11-7.2)
		2	13	61	2.6 (1.4-5.1)	3 (1.5-5.9)	2	14	1.3 (0.29-6.1)	1.9 (0.39-9.3)
	mRNA-1273	1	2	9	2.4 (0.52-11)	2.4 (0.52-11)	0	2	-	-
		2	9	7	16 (5.6-45)	21 (7-64)	2	3	6.4 (1.1-39)	8 (1.1-57)
Overall	Unexposed		830	10,580	Reference	Reference	248	2,762	Reference	Reference
	BNT162b2	1	43	293	1.9 (1.4-2.7)	2 (1.4-2.8)	8	77	1.2 (0.55-2.5)	1.3 (0.57-2.8)
		2	184	361	7.6 (6.2-9.4)	8.7 (7-11)	27	78	4.3 (2.7-7)	5.9 (3.6-9.6)
	mRNA-1273	1	6	38	2.1 (0.88-5.1)	2.3 (0.96-5.6)	3	10	3.4 (0.92-12)	6.3 (1.6-25)
		2	90	39	32 (22-48)	34 (23-51)	16	12	14 (6.8-31)	17 (7.6-37)

[a] Odd-ratio (95% confidence interval) were obtained from univariable conditional logistic regression, adjusting for matching variables (sex, age and department of residence). [b] Odd-ratio (95% confidence interval) were obtained from multivariable conditional logistic regression, adjusting for matching variables (sex, age and department of residence), deprivation index, previous event in past 5 years of myocarditis, and history of SARS-CoV-2 infections in the month preceding the index date. Odds-ratio could not be calculated in categories where no case exposed to vaccine was recorded.

Supplementary Appendix to Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines

This study is limited by using hospital discharge diagnosis. In doing so, the study does not include those who may have died prior to hospitalization or those whose symptoms were not severe enough to be hospitalized. There have been reports of autopsy proven myocarditis after vaccination. There have also been anecdotal evidence of patients being dismissed by (Emergency Room) ER and never being hospitalized. In my own cardiology practice I have seen

patents for VAM who were dismissed from the ER and never hospitalized. Adjusting for these excluded subsets may yield even higher risk than reported in this study. Follow-up of the patients in this study was limited to one month after discharge. Longer follow-up is warranted because persistent abnormalities on cardiac MRI are present in 75% of adolescents 3–8 months after COVID-19 mRNA vaccination.


JAMA Network Open
Original Investigation | Public Health
Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada
Sarah A. Buchan, PhD; Chi Yon Seo, MSc; Caitlin Johnson, MPH; Sarah Alley, MPH; Jeffrey C. Kwong, MD; Sharifa Nasreen, PhD; Andrew Calzavara, MSc; Diane Lu, MD; Tara M. Harris, MHSc; Kelly Yu, MPH; Sarah E. Wilson, MD

Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada

Using population based passive surveillance from Ontario, Canada, this peer reviewed study assessed rates of reported myocarditis or pericarditis following receipt of a COVID-19 mRNA vaccines. As other studies have also found, the rate of myocarditis was greater in younger males than females, and greater after the second dose than after first dose. Data presented at CDC's ACIP meeting June 23 and data from this preprint study (not yet peer reviewed) both found *incremental increased risk* of myocarditis after the booster; however, this study did not assess the rate of myocarditis after booster vaccination. No details are provided regarding presence of obesity or any other medical conditions on the patients in the study. Prior infection status is also not known about the study participants.

The study found myocarditis occurred at a rate of 97.3 per million doses of BNT162b2 (Pfizer) for 12–17-year-old males and 299.5 per million doses of mRNA-1273 (Moderna) for 18–24-year-old males. As the authors also mention in the discussion, *this is substantially higher than the VAERS data* reported by CDC (38.5 per million for mRNA-1273 doses in males and 69.1 per million BNT162b2 doses for males 16–17 years old). Furthermore, the authors continue, using data from four claims databases, FDA reported a rate of 283 cases of myocarditis per million of mRNA-1273 doses for males 18–25 years old. This is closer to the rate found in this study (299.5 per million). Vaccine Safety Datalink (VSD) data, the authors note, found the adjusted rate of myocarditis or pericarditis to be 2.72 times greater for dose 2 of mRNA-1273 than dose 2 of BNT162b2 (i.e, Moderna's mRNA COVID-19 vaccine has almost 3 times the rate as Pfizer's mRNA COVID-19 vaccine). CDC's continued reliance on VAERS data alone for its risk-benefit analysis then is either incompetence or intentional data manipulation to control the narrative.

Table 2. Crude Rate of Reported Myocarditis or Pericarditis per Million Vaccine Doses Administered by Vaccine Product, Dose Number, Age, and Sex With Series Initiation on or After June 1, 2021

	Reported No. of cases per 1 000 000 doses, No. (95% CI)[a]					
	All individuals		Female individuals		Male individuals	
Vaccine	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
BNT162b2						
Age group, y						
12-17	27.3 (14.9-45.8)	54.4 (34.5-81.7)	20.1 (6.5-47.0)	9.7 (1.2-35.1)	34.2 (15.6-64.9)	97.3 (60.3-148.8)
18-24	17.9 (5.8-41.7)	44.3 (17.8-91.3)	7.9 (0.2-44.1)	27.4 (3.3-99.0)	26.2 (7.1-67.0)	59.2 (19.2-138.1)
25-39	13.0 (5.2-26.8)	16.0 (5.2-37.4)	3.9 (0.1-21.6)	19.7 (4.1-57.6)	21.5 (7.9-46.7)	12.6 (1.5-45.4)
≥40	5.9 (1.2-17.3)	NR	4.0 (0.1-22.3)	NR	7.8 (0.9-28.3)	NR
Total	15.6 (10.4-22.4)	29.0 (20.2-40.3)	8.9 (3.9-17.6)	11.9 (4.8-24.5)	21.8 (13.5-33.3)	45.3 (30.1-65.5)
mRNA-1273						
Age group, y						
12-17[b]	NA	NA	NA	NA	NA	NA
18-24	21.6 (2.6-77.9)	195.5 (117.7-305.3)	NR	69.1 (14.2-201.9)	37.2 (4.5-134.6)	299.5 (171.2-486.4)
25-39	16.2 (3.3-47.3)	58.7 (30.3-102.6)	NR	21.5 (2.6-77.7)	28.8 (5.9-84.3)	90.1 (43.2-165.7)
≥40	30.0 (11.0-65.2)	NR	22.0 (2.7-79.4)	NR	36.7 (10.0-93.9)	NR
Total	23.0 (11.5-41.1)	62.5 (42.4-88.6)	9.5 (1.1-34.2)	22.0 (7.1-51.4)	33.7 (15.4-64.0)	96.8 (63.2-141.9)

Abbreviations: BNT162b2, Pfizer-BioNTech Comirnaty; mRNA-1273, Moderna Spikevax; NA, not applicable; NR, not reported.

[a] Estimates were not provided for strata with 0 reported events.

[b] Estimates for mRNA-1273 were not provided for individuals aged 12 to 17 years because this product was not used for this age group in Ontario.

Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada

In response to questions about COVID-19 vaccine interchangeability (i.e., dose 1 and dose 2 are different COVID-19 vaccine manufacturers), CDC's Interim Clinical Considerations state, "In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, *any* age-appropriate mRNA COVID-19 vaccine product may be administered…" (empahsis mine). Regarding the booster, CDC's recommendations state "Any age-appropriate mRNA vaccine can be used for the booster dose(s): it can be the same mRNA vaccine as the primary series (homologous booster dose) or a different mRNA vaccine (heterologous booster dose)." However, In the Supplementary Online Content of this study, the authors report that when vaccines are mixed (i.e., dose 1 and dose 2 are different manufacturers), the rate of myocarditis can be as high as *777 per million* if mRNA-1273 is the second dose after initial BNT162b2 dose!!! The risk with heterologous dosing thus is 2.67 times higher than homologous dosing. The study found the risk to be considerably lower with longer interval dosing (i.e., longer than 30 days). Clearly, mixing vaccine manufacturers must be done with extreme caution with strong consideration for longer interval between dose 1 and dose 2.

eTable 5. Rates[a] of reported myocarditis and pericarditis per million doses administered and 95% CI among males aged 18-24 years by vaccine product and interdose interval with dose 2 on or after June 1, 2021

Vaccine schedule	Reports (N)	Doses administered (N)	**Reported rate (95% CI) per million doses**
People with two doses			
Homologous schedule			
BNT162b2-BNT162b2	11	235,819	46.6 (23.3 – 83.5)
Interval ≤30 days	2	21,160	94.5 (11.4 – 341.4)
Interval 31-55 days	8	124,235	64.4 (27.8 – 126.9)
Interval ≥56 days	1	90,424	11.1 (0.3 – 61.6)
mRNA-1273-mRNA-1273	27	93,616	288.4 (190.1 – 419.6)
Interval ≤30 days	4	10,623	376.5 (102.6 – 964.1)
Interval 31-55 days	20	60,352	331.4 (202.4 – 511.8)
Interval ≥56 days	3	22,641	132.5 (27.3 – 387.2)
Heterologous schedule			
mRNA-1273-BNT162b2	0	8,853	NR
Interval ≤30 days	0	1,058	NR
Interval 31-55 days	0	5,402	NR
Interval ≥56 days	0	2,393	NR
BNT162b2-mRNA-1273	29	85,893	337.6 (226.1 - 484.9)
Interval ≤30 days	6	7,720	777.2 (285.2 - 1691.6)
Interval 31-55 days	20	62,717	318.9 (194.8 - 492.5)
Interval ≥56 days	3	15,456	194.1 (40.0 - 567.2)

[a] Estimates were not provided for strata with 0 reported events. NR, not reported.

Supplementary Appendix to Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada

Research

JAMA Cardiology | Original Investigation

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents

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This Nordic cohort study followed 23 million residents 12 years and older from December 27, 2020 through October 27, 2021. “Data on SARS-CoV-2 vaccinations, hospital diagnoses of myocarditis or pericarditis, and covariates forthe participants were obtained from linked nationwide health registers in Denmark, Finland, Norway, and Sweden.” Outcomes (myocarditis or pericarditis) were assessed by hospital discharge diagnosis and were limited to incidents occurring within 28 days of vaccination. The study is limited by hospital discharge diagnosis, not accounting for those who might died before hospitalization or not been hospitalized. Since spike protein has been found in circulation even four months after injection, limiting the study to outcomes within 28 days after vaccination may not capture the full extent of the morbidity.

The study found both first and second doses of mRNA vaccines were associated with increased risk of myocarditis and pericarditis across all ages 12 years and older. In biostatistics, the Incidence Rate Ratio (IRR) = Number of new cases during the follow up period / Total person-time by disease free individuals. The study found IRR for BNT12b2 was 2.04 (i.e., twice as many in the vaccinated group as the unvaccinated group) and 8.55 for mRNA-1273 (8 times as many incidents in the vaccinated group compared to the unvaccinated group). For individuals receiving 2 doses of the same vaccine, risk of myocarditis was highest among young males (aged 16–24 years) after the second dose (IRR 5.31 for BNT126b2 and 13.83 for mRNA-1273). The increased risk was not limited to adolescents and young adults; the IRR for 25–39 year old males was 12.96 (i.e., almost *13 times greater incidence* in the vaccinated group compared to the unvaccinated group).

As in the study discussed above, heterologous dosing was associated with even high risk than homologous dosing. *IRR was 35.62 for 16–24 year old males (compared to 13.83 for homologous dosing), and 23.13 for 25–39 year old males (compared to 12.95 for homolougous dosing) if mRNA-1273 was the second dose after first dose of BNT126b2*. Heterologous dosing thus further increases the risk of myocarditis, *yielding a risk 2.57 times greater for 16- 24 year old males and 1.78 times greater for 25–39 year old males*. As noted above, mixing vaccine manufacturers must be done with extreme caution.

Overall, the study findings suggest between *40 and 70* ***excess*** *events in 28 days per million* vaccine recipients after BNT162b2, and between *90 and 280* ***excess*** *events per million* vaccine recipients after mRNA-1273. The authors conclude that “[t]his risk should be balanced against the benefits of protecting against severe COVID-19 disease.” Thus far, CDC does not seem to be balancing this risk with the putative benefits of COVID-19 vaccination in healthy children and young adults.

Table 2. Myocarditis Within 28 Days After a Dose of SARS-CoV-2 Vaccine[a]

Subgroup, exposure[b]	No. of events[c]	Follow-up, 1000 person-years	Crude incidence rate per 1000 person-years of follow-up[d]	IRR (95% CI)	No. of excess events in 28 d per 100 000 vaccinees (95% CI)
Males, ages ≥12 y					
Unvaccinated	520	5340.6	0.097	1 [Reference]	0 [Reference]
AZD1222	6	43.0	0.139	2.39 (1.04 to 5.48)	0.62 (0.00 to 1.24)
AZD1222/AZD1222	≤5	29.2	ND	1.29 (0.31 to 5.33)	0.12 (−0.48 to 0.72)
BNT162b2	70	560.9	0.125	1.40 (1.09 to 1.80)	0.27 (0.09 to 0.46)
BNT162b2/BNT162b2	85	495.0	0.172	2.04 (1.61 to 2.58)	0.67 (0.46 to 0.88)
BNT162b2/mRNA-1273	34	23.7	1.433	16.99 (11.51 to 25.07)	10.34 (6.86 to 13.83)
mRNA-1273	13	93.2	0.139	1.45 (0.84 to 2.52)	0.33 (−0.11 to 0.78)
mRNA-1273/mRNA-1273	53	72.3	0.733	8.55 (6.40 to 11.41)	4.97 (3.62 to 6.32)
Males, ages 16-24 y					
Unvaccinated	149	794.6	0.188	1 [Reference]	0 [Reference]
AZD1222	0	0.70	ND	ND	ND
AZD1222/AZD1222	0	0.10	ND	ND	ND
BNT162b2	24	63.9	0.376	2.16 (1.40 to 3.33)	1.55 (0.70 to 2.39)
BNT162b2/BNT162b2	37	41.5	0.891	5.31 (3.68 to 7.68)	5.55 (3.70 to 7.39)
BNT162b2/mRNA-1273	17	4.6	3.687	35.62 (18.87 to 67.25)	27.49 (14.41 to 40.56)
mRNA-1273	≤5	11.5	ND	2.90 (1.05 to 7.97)	1.75 (−0.20 to 3.71)
mRNA-1273/mRNA-1273	15	5.8	2.584	13.83 (8.08 to 23.68)	18.39 (9.05 to 27.72)
Males, ages 25-39 y					
Unvaccinated	146	1440.6	0.101	1 [Reference]	0 [Reference]
AZD1222	0	3.1	ND	ND	ND
AZD1222/AZD1222	0	0.5	ND	ND	ND
BNT162b2	17	109.2	0.156	1.62 (0.94 to 2.80)	0.46 (0.00 to 0.92)
BNT162b2/BNT162b2	15	83.9	0.179	1.75 (1.03 to 2.99)	0.59 (0.07 to 1.10)
BNT162b2/mRNA-1273	15	9.7	1.543	23.16 (12.60 to 42.59)	11.33 (5.59 to 17.07)
mRNA-1273	≤5	30.6	ND	1.27 (0.40 to 3.99)	0.16 (−0.55 to 0.86)
mRNA-1273/mRNA-1273	26	23.0	1.132	12.96 (8.23 to 20.42)	8.01 (4.92 to 11.11)
Males, ages ≥40					
Unvaccinated	206	2657.6	0.078	1 [Reference]	0 [Reference]
AZD1222	6	39.3	0.153	2.30 (0.99 to 5.33)	0.66 (−0.02 to 1.34)
AZD1222/AZD1222	≤5	28.6	ND	1.24 (0.30 to 5.18)	0.10 (−0.53 to 0.74)
BNT162b2	27	375.8	0.072	0.93 (0.62 to 1.40)	−0.04 (−0.28 to 0.20)
BNT162b2/BNT162b2	31	363.6	0.085	1.08 (0.74 to 1.57)	0.05 (−0.19 to 0.28)
BNT162b2/mRNA-1273	≤5	9.4	ND	3.54 (0.85 to 14.79)	1.17 (−0.58 to 2.93)
mRNA-1273	6	48	0.125	1.89 (0.84 to 4.28)	0.45 (−0.10 to 1.00)
mRNA-1273/mRNA-1273	11	43.3	0.254	3.45 (1.87 to 6.35)	1.38 (0.50 to 2.27)

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents

The supplementary appendix notes a 4.8% all cause mortality within 28 days amongst all males (all age groups) in the study population who received 2 doses of mRNA-1273, presumably in those over 40 years old (i.e., none of the deaths occurred in those less 40 years old). As previously discussed here, animal models have shown an association with sustained aerobic exercise and increased risk of death. Because of this and the known association of myocarditis with sudden death in young athletes, current guidelines from the 2005 Bethesda Conference for activity with acute myocarditis recommend *activity restriction from competitive athletics and other vigorous exercise for at least 6 months*. Therefore, limiting all-cause mortality analysis to 28 days *may* be under estimating the true mortality risk.

Contrary to CDC's repeated insistence that most cases of myocarditis after vaccination were "generally mild", this Nordic study found 48% of all males (i.e., all age groups) were hospitalized longer than 3 days (i.e, discharged day 4 or later). All the males 16–24 years old were discharged within three days, whereas, only 60% of the males 25–39 years old were discharged within 3 days (i.e., 40% were discharged at day 4 or later). No details are provided on the percent requiring intensive care unit (ICU) care, pressor support (medications to support blood pressure in cardiogenic shock), or any persistent abnormalities on imaging. Furthermore, no data are available on 6-month follow-up of functional capacity (i.e., residual symptoms, exercise capacity).

eTable 11. Mortality and Discharge Outcomes Among Myocarditis Cases

Kaplan-Meier estimates combined from all four Nordic countries in meta-analysis with random effects[a].

	Unvacc.[a]	BNT162b2[a]	BNT162b2/ BNT162b2[a]	mRNA-1273[a]	mRNA-1273/ mRNA-1273[a]
All	Percent, (95% CI)	Percent, (95% CI)	Percent, (95% CI)	Percent, (95% CI)	Percent, (95% CI)
Discharged day 4 or later[b]	53.0 (38.0-67.5)	54.0 (32.1-74.6)	53.1 (35.1-70.3)	41.7 (22.5-63.7)	42.6 (31.7-54.3)
Death within 28 days[c]	0.8 (0.3-2.0)	2.3 (0-6.8)	0.2 (0.0-0.4)	NA	4.5 (0.0-13.2)
Females					
Discharged day 4 or later[b]	56.9 (43.7-68.9)	48.3 (33.2-63.7)	53.5 (34.7-71.3)	NA	NA
Death within 28 days[c]	2.9 (0.0-18.6)	6.3 (0.0-18.1)	0.2 (0.0-0.7)	4.8 (0.0-13.4)	0 (0-0)
Males					
Discharged day 4 or later[b]	50.9 (35.5-66.1)	52.4 (28.9-74.8)	49.8 (31.2-68.5)	37.8 (20.5-58.9)	48.5 (26.5-71.1)
Death within 28 days[c]	0.8 (0.3-1.9)	0 (0-0)	0 (0-0)	NA	4.8 (0.0-13.9)
Males aged 16-24 years					
Discharged day 4 or later[b]	45.4 (28.8-63.1)	29.6 (8.4-65.7)	42.1 (20.4-67.4)	NA	NA
Death within 28 days[c]	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
Males aged 25-39 years					
Discharged day 4 or later[b]	51.8 (29.2-73.7)	44.2 (18.6-73.3)	27.2 (22.1-32.9)	NA	40.6 (12.5-76.5)
Death within 28 days[c]	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)

[a] Cases included from the 0-28 day time window following vaccination among vaccinated. To combine country-specific estimates the log odds of probabilities were then used as inputs in meta-analysis. Where the confidence interval limits were 0% or 100%, we used the point estimate multiplied by 0.1 or (100-0.1*(100-point estimate)), respectively. If some country-specific estimates were exactly 0, but no country-specific estimate was higher than 20%, then the maximal estimate and upper confidence limit were given as result. Cells marked 'NA' is due to heterogeneity or lack of outcome estimation in individual Nordic countries.

[b] Day of admission is day 0.

[c] Death within 28 days of outcome from any cause.

Supplementary Appendix from SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents

Clinical Infectious Diseases

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Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination

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In a population cohort , this study from Hong Kong aimed at identifying all suspected cases of acute myocarditis in adolescents aged between 12 and 17 years who received the Comirnaty vaccine between June 14, 2021 and September 4, 2021. All suspected cases of acute myocarditis/pericarditis that occur within 14 days after receiving either the first or the second dose of the Comirnaty vaccine and admitted to one of the HA hospitals were reported to the Advanced Incident Reporting System (AIRS) on admission and the basis for this analysis. Vaccination records within the study period were extracted from the Department of Health (DH) in Hong Kong since the commencement of mass COVID-19 vaccinations in adolescents aged 12–17 years. Follow-up period was minimum 14 days. Patients with prior history of myocarditis / pericarditis were excluded. None of the reported cases had prior COVID-19 infection as evidenced by negative SARS-CoV2 PCR and nucleocapsid antibodies.

The study found 33 cases of myocarditis/pericarditis within 14 days following vaccination with Comirnaty. “All of them presented with chest pain. Three cases (9.09%) had normal troponin levels, 2 of them were cases of definite pericarditis and 1 had possible myocarditis. Six (18.18%) had normal ECGs, 25 (75.76%) had normal echocardiograms, and 7 (21.88%) had normal cMRI,” noted the authors. The incidence was higher in males than females, and found to be *322.9 per million*. The incidence was even higher after second dose (*373.2 per million*) than first dose (55.7 per million). The study compared these rates to background incidence rate in 2020 and found the incidence rate difference to be *371.1 per million* after second dose in adolescent males (Table 2 and Table 3 below). The incidence rates found in this study were much higher than CDC’s estimates based upon VAERS and even VSD.

Table 2. Incidence Rate Differences of Myocarditis/Pericarditis Cases Following Comirnaty Vaccination Stratified by Sex and Compared to Background Rate in 2020

	Incidence Rate (per 100 000 person-14 days, 95% CI)		Background Incidence Rate in 2020[a] (per 100 000 person-14 days, 95% CI)		Incidence Rate Difference (per 100 000 person-14 days, 95% CI)
Comirnaty					
Total	18.52 (11.67–29.01)		0.11 (.01–20.36)		**18.41 (9.95–26.87)**
Male	32.29 (22.78–45.4)	**322.9 per million**	0.21 (.01–10.34)	**320.8 per million**	**32.08 (20.91–43.25)**
Female	4.53 (1.76–11.11)		0		-

Values in bold represent a statistically significant difference ($P < .05$).

Abbreviation: CI, confidence interval.

[a]The background incidence rates were calculated using the reporting period [14 June to 4 September] in 2020 and truncated to incidence rate per 14 days.

Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination

Table 3. Incidence Rate Differences of Myocarditis/Pericarditis Cases Following the First and Second Doses of Comirnaty Vaccination Stratified by Sex and Compared to Background Rate in 2020

	Incidence Rate (per 100,000 person-14 days, 95% CI)		Background Incidence Rate in 2020[a] (per 100 000 person-14 days, 95% CI)		Incidence Rate Difference (per 100 000 person-14 days, 95% CI)
First dose of Comirnaty					
Total	3.37 (1.12–9.51)		0.11 (.01–20.36)		3.26 (−0.40 to 6.92)
Male	5.57 (2.36–12.53)		0.21 (.01–10.34)		**5.36 (0.65–10.07)**
Females	1.13 (0.16–6.58)		0		-
Second dose of Comirnaty					
Total	21.22 (13.78–32.28)	212.2 per million	0.11 (.01–20.36)	211.1 per million	**21.11 (12.06–30.16)**
Male	37.32 (26.98–51.25)	373.2 per million	0.21 (.01–10.34)	371.1 per million	**37.11 (25.10–49.12)**
Female	4.77 (1.90–11.44)		0		-

Values in bold represent a statistically significant difference ($P < .05$).

Abbreviation: CI, confidence interval.

[a]The background incidence rates were calculated using the reporting period (14 June to 4 September) in 2020 and truncated to incidence rate per 14 days.

Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination

The study's strength is its comprehensive analysis (all patients had imaging and laboratory evaluation, unlike many of the studies in the US where diagnostic evaluation for suspected VAM does not seem to be standardized). The authors acknowledge the study's limitation in not capturing those with mild symptoms not leading to medical evaluation. The study does not enumerate the percent of patients needing ICU level care. No data are available on follow-up beyond 14 days.

MYOCARDITIS AFTER SARS-COV2 INFECTION

CDC continues to insist that COVID-19 can also cause myocarditis, that the incidence of myocarditis after SARS-CoV2 infection is greater than after vaccination, and that the benefits of COVID-19 vaccination outweigh the risks. CDC therefore recommends that all persons 6 months and older be vaccinated against COVID-19.

CDC MMWR on Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination anlaysed EHR data from 40 health care systems, which is more comprehensive than VSD (9 integrated health systems) and certainly more comprehensive than passive reporting in VAERS. "Analysis of EHR data from 40 U.S. health care systems found that the incidences of cardiac complications after SARS-CoV-2 infection or mRNA COVID-19 vaccination were low overall but were higher after infection than after vaccination for both males and females in all age groups", the MMWR concluded.

TABLE 2. Incidence of cardiac outcomes among males aged ≥5 years after SARS-CoV-2 infection or mRNA COVID-19 vaccination and risk ratios, by age group and risk window — National Patient-Centered Clinical Research Network, United States, January 1, 2021–January 31, 2022

Age group, yrs/ Outcome/ Risk window	Incidence* among males					Risk ratio (95% CI) SARS-CoV-2 infection versus mRNA COVID-19 vaccination			
		mRNA COVID-19 vaccination cohort				mRNA COVID-19 vaccination cohort			
	SARS-CoV-2 infection cohort†	First dose§	Second dose§	Unspecified dose¶	Any dose**	First dose§	Second dose§	Unspecified dose¶	Any dose**
5–11††									
Myocarditis									
7-day	12.6	0	0	0	0	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5–35.7)	NC	2.7 (0.3–22.1)	5.4 (1.1–26.1)
Myocarditis or pericarditis									
7-day	12.6	0	0	0	0	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5–35.7)	NC	2.7 (0.3–22.1)	5.4 (1.1–26.1)
Myocarditis, pericarditis, or MIS§§									
7-day	93.0	—¶¶	—	—	—	NC	NC	NC	NC
21-day	103.0	—	—	—	—	25.7 (3.5–187.0)	NC	16.0 (2.2–116.0)	31.7 (7.7–131.2)
42-day	133.2	—	—	—	—	33.3 (4.6–240.5)	28.2 (3.9–203.9)	10.3 (2.5–42.3)	20.5 (7.4–56.7)
12–17††	Does not adjust for 75% children infected (CDC seroprevalence data)								
Myocarditis									
7-day	50.1	2.2	22.0	16.7	12.9	23.0 (5.3–99.5)	2.3 (1.2–4.4)	3.0 (1.3–6.7)	3.9 (2.1–7.0)
21-day	59.0	3.3	26.7	20.4	16.0	18.0 (5.4–60.6)	2.2 (1.2–4.0)	2.9 (1.4–6.0)	3.7 (2.1–6.4)
Myocarditis or pericarditis									
7-day	56.0	2.2	26.7	22.3	16.0	25.7 (6.0–110.3)	2.1 (1.1–3.9)	2.5 (1.2–5.2)	3.5 (2.0–6.1)
21-day	64.9	3.3	35.9	29.7	21.6	19.8 (5.9–66.2)	1.8 (1.0–3.1)	2.2 (1.1–4.2)	3.0 (1.8–5.0)
Myocarditis, pericarditis, or MIS§§									
7-day	150.5	—	—	—	—	69.0 (16.8–283.2)	5.6 (3.5–9.2)	6.8 (3.6–12.7)	9.4 (6.2–14.4)
21-day	159.3	—	—	—	—	48.7 (15.2–155.7)	4.4 (2.9–6.9)	5.4 (3.1–9.4)	7.4 (5.0–10.8)
42-day	180.0	—	—	—	—	4.9 (3.2–7.4)	4.6 (3.0–6.9)	5.4 (3.2–9.1)	4.9 (3.5–6.7)
18–29									
Myocarditis									
7-day	55.3	0.9	6.5	7.0	4.6	61.8 (8.5–451.8)	8.5 (3.7–19.1)	7.9 (3.3–19.0)	12.0 (6.4–22.5)
21-day	63.7	3.6	8.4	11.6	7.5	17.8 (6.4–49.8)	7.6 (3.7–15.7)	5.5 (2.7–11.0)	8.4 (5.0–14.2)
Myocarditis or pericarditis									
7-day	85.5	2.7	12.1	22.0	11.5	31.8 (9.9–102.0)	7.0 (3.8–12.9)	3.9 (2.3–6.6)	7.4 (4.8–11.5)
21-day	100.6	8.1	15.0	27.8	16.1	12.5 (6.2–25.2)	6.7 (3.9–11.7)	3.6 (2.3–5.8)	6.3 (4.3–9.1)
Myocarditis, pericarditis, or MIS§§									
7-day	97.2	—	—	—	—	36.2 (11.3–115.5)	8.0 (4.4–14.6)	4.4 (2.6–7.4)	8.5 (5.6–12.9)
21-day	112.3	—	—	—	—	13.9 (7.0–28.0)	7.5 (4.4–13.0)	4.0 (2.5–6.4)	7.0 (4.8–10.1)
42-day	140.8	—	—	—	—	7.2 (4.5–11.4)	8.4 (5.0–13.9)	4.5 (2.9–6.9)	6.4 (4.6–8.8)
≥30									
Myocarditis									
7-day	57.2	0.9	0.5	3.0	1.3	67.2 (31.4–143.8)	115.2 (42.6–311.7)	18.9 (11.2–31.7)	45.7 (30.2–69.2)
21-day	63.0	1.9	1.2	4.2	2.2	32.4 (19.3–54.3)	50.8 (26.7–96.4)	15.1 (9.7–23.7)	28.3 (20.4–39.3)
Myocarditis or pericarditis									
7-day	100.2	3.8	3.1	15.0	6.3	26.6 (18.2–38.7)	32.3 (21.3–48.8)	6.7 (5.2–8.6)	16.0 (12.9–19.8)
21-day	114.0	7.3	7.3	20.1	10.4	15.6 (11.8–20.7)	15.6 (11.7–20.7)	5.7 (4.5–7.1)	10.9 (9.1–13.1)
Myocarditis, pericarditis, or MIS§§									
7-day	109.1	—	—	—	—	28.9 (19.9–42.0)	35.1 (23.3–53.0)	7.3 (5.7–9.4)	17.4 (14.1–21.5)
21-day	123.0	—	—	—	—	16.8 (12.7–22.3)	16.8 (12.7–22.2)	6.1 (4.9–7.7)	11.8 (9.9–14.0)
42-day	136.8	—	—	—	—	10.7 (8.6–13.4)	10.8 (8.6–13.5)	5.4 (4.4–6.7)	8.7 (7.4–10.1)

Abbreviations: MIS = multisystem inflammatory syndrome; NC = not calculated.

* Cases per 100,000 persons.

† Persons in the infection cohort included those who received ≥1 positive SARS-CoV-2 molecular or antigen test result.

§ The first dose cohort included persons who had either the first of 2 doses ≥20 days before a second dose or a specific code for a first dose; the second dose cohort included persons who had either the second of 2 doses ≥20 days after a first dose or a specific code for a second dose.

¶ The unspecified dose cohort included persons who had a single dose that was not specified as a first or second dose; doses specified as booster doses were excluded.

** The any dose cohort is the first, second, and unspecified dose cohorts combined; persons who had 2 doses are represented twice in the cohort but had different index dates for their first and second doses.

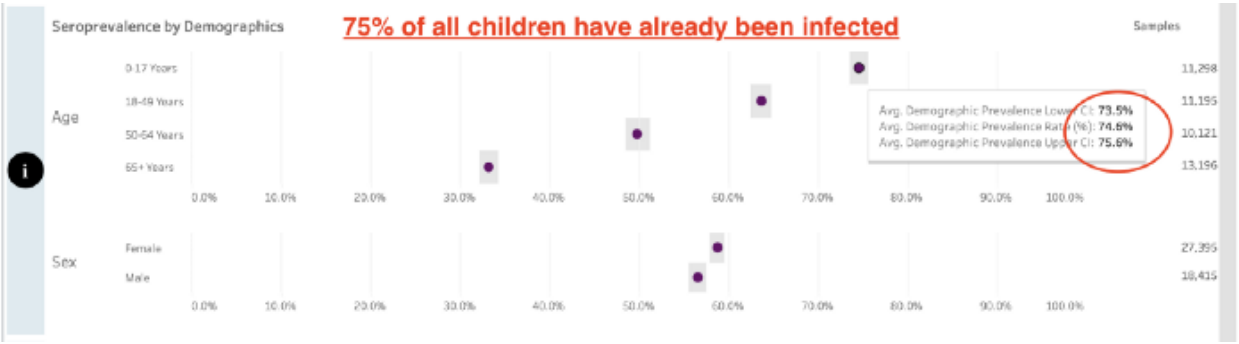
†† BNT162b2 (Pfizer-BioNTech) is the only mRNA COVID-19 vaccine approved for persons aged 5–17 years.

§§ Diagnoses of myocarditis, pericarditis, or MIS after a positive SARS-CoV-2 test result compared with diagnoses of myocarditis or pericarditis after vaccination. The 42-day risk ratios were only calculated for this outcome and comparison. The incidence of myocarditis or pericarditis in this risk window was 4.0, 37.1, 19.7, and 12.8 cases per 100,000 for males aged 5–11, 12–17, 18–29, and ≥30 years after a first dose of an mRNA COVID-19 vaccine; 4.7, 39.4, 16.8, and 12.7 cases per 100,000 after a second dose; 12.9, 33.4, 31.3, and 25.3 cases per 100,000 after an unspecified dose; and 6.5, 37.1, 22.0, and 15.8 cases per 100,000 after any dose.

¶¶ Dashes indicate the incidence for vaccination cohorts was not applicable because the comparison for incidence of myocarditis, pericarditis, or MIS after infection was to myocarditis or pericarditis after vaccination.

An egregious flaw in the study design is in how it defines the infection cohort: “persons who received ≥1 positive SARS-CoV-2 molecular or antigen test result”. CDC’s own seroprevalence data demonstrates that 75% of all children in the US have already been infected by

SARS-CoV2. This data implies that 54 million children have already been infected, which is 4.5 times greater than the 12 million officially confirmed PCR+ ‘cases.



Nationwide COVID-19 Infection-Induced Antibody Seroprevalence (Commercial laboratories)

If the MMWR data on myocarditis after SARS-CoV2 infection were adjusted by 4.5 times (divided by 4.5), then the rate would be about *half* the rate of myocarditis after vaccination. This flaw in study design is not merely a ‘limitation’ of the study; it is a fatal flaw that stultifies the study and unequicoably nullifies the conclusions.

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Article

The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients—A Large Population-Based Study

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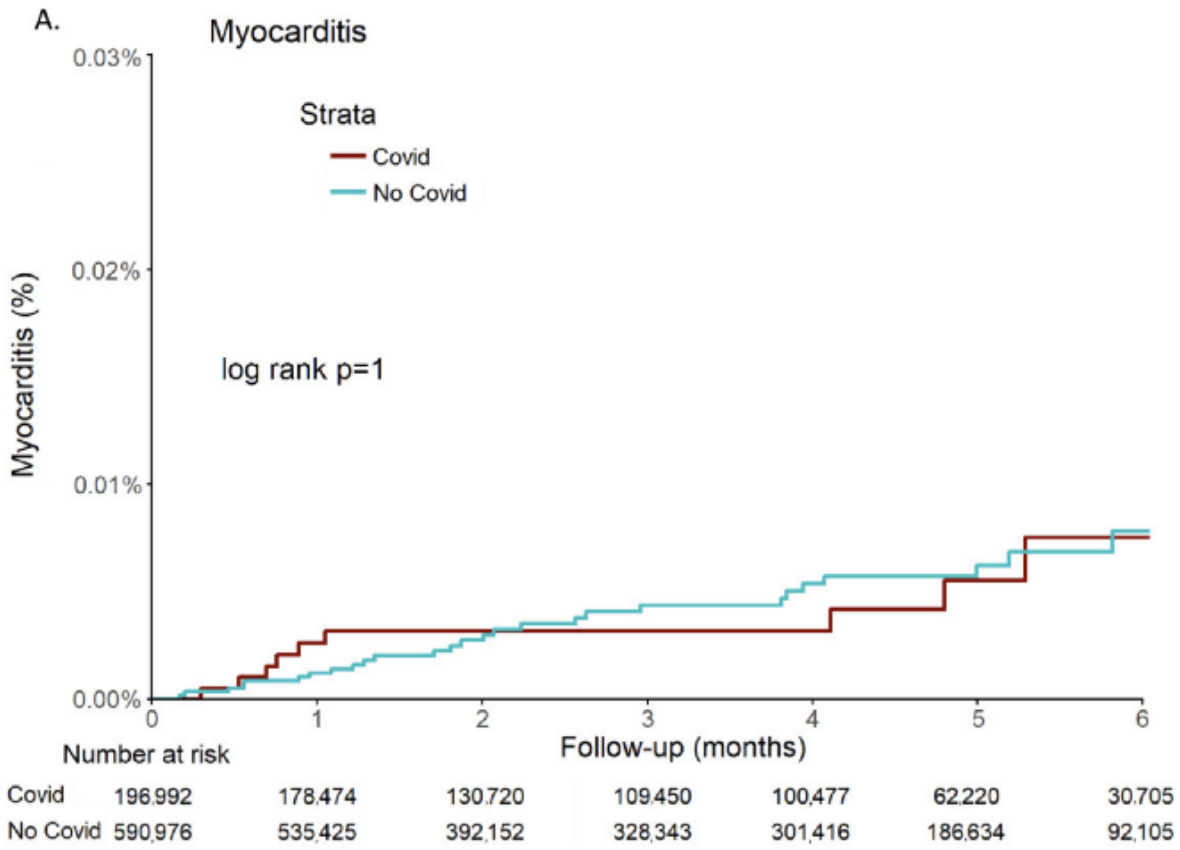
In a retrospective cohort study of 196,992 adults after COVID-19 infection in Clalit Health Services members in Israel between March 2020 and January 2021 patients were followed for six months. “Inpatient myocarditis and pericarditis diagnoses were retrieved from day 10 after positive PCR. The control cohort of 590,976 adults with at least one negative PCR and no positive PCR were age- and sex-matched.” The study population has 27% obesity, whereas obesity prevalence in US is 42%. Thus caution must be applied in generalizing this study to US population.

The study found *age* (aHR 0.96; p =0.045) and the *male sex* (aHR 4.42; p = 0.003) were independently associated with myocarditis. *Obesity was borderline associated* with myocarditis (aHR 2.31; p = 0.053). *Most notably,* ***COVID-19 infection was not associated with myocarditis*** (aHR 1.08; 95% CI 0.45 to 2.56, p = 0.869). This study supports the interpretation above that findings from CDC MMWR ought to be adjusted seroprevalence data (i.e., infection cohort denominator needs to be adjusted by 4.5 times to account for the seroprevalence data). Without the adjustment for seroprevalence data, CDC erroneously concludes that myocarditis after SARS-CoV2 infection occurs at a greater rate than after vaccination.



[The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients — A Large Population-Based Study]

Table 3. Adjusted HRs for myocarditis and pericarditis.

	Myocarditis		Pericarditis	
	aHR (95% CI)	*p*-Value	aHR (95% CI)	*p*-Value
COVID-19	1.08 (0.45–2.56)	0.869	0.53 (0.25–1.13)	0.100
Age	**0.96 (0.93–1.00)**	**0.045 ***	1.01 (0.99–1.03)	0.537
Sex (male)	**4.42 (1.64–11.96)**	**0.003 ***	**1.93 (1.09–3.41)**	**0.025 ***
BMI	1.00 (0.97–1.04)	0.935	1.00 (0.94–1.06)	0.897
Diabetes	1.15 (0.26–5.00)	0.856	0.97 (0.43–2.21)	0.950
Hyperlipidemia	0.33 (0.08–1.43)	0.139	1.13 (0.54–2.38)	0.749
Obesity	2.31 (0.99–5.41)	0.053	1.32 (0.64–2.71)	0.448
CKD	3.80 (0.82–17.66)	0.088	1.91 (0.72–5.05)	0.191
Smoking (Now)	1.62 (0.65–4.06)	0.304	0.85 (0.42–1.74)	0.661
Smoking (Past)	1.85 (0.61–5.64)	0.277	0.73 (0.33–1.63)	0.439
PVD	1.35 (0.14–12.84)	0.793	**4.20 (1.50–11.72)**	**0.006 ***
ACS	3.93 (0.76–20.40)	0.104	1.52 (0.61–3.80)	0.366
Hypertension	1.46 (0.36–5.87)	0.592	0.88 (0.38–2.06)	0.770

CKD = chronic kidney disease. PVD = peripheral vascular disease. ACS = acute coronary syndrome. * Statistically significant results are highlighted in bold.

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SUMMARY

The background rate of myocarditis in general population is 8 per million for all children and 18 per million for 15–18 year old adolescents. Using primarily VAERS data, CDC estimates the risk of VAM to be about 40 per million. CDC's own MMWR analyzing EHR from 40 health care systems found the rate to be 267 per million after second dose for 12–17 year old male. Other studies have found a rate of approximately 300 per million for 16–24 males after second dose of mRNA vaccination. The rate is further increased with heterologous dosing if mRNA-1273 is second dose within 30 days after BNT126b2 first dose (777 per million). The rates of VAM is in fact far greater than after COVID-19 infection when one adjusts for seroprevalence data in children. Continued insistence that everyone be vaccinated regardless of risk stratification or prior infection is an egregious affront to medical ethics and is dangerously jeopardizing the health and lives of children and young adults. **School and college mandates ought to cease and desist immediately, lest we further unleash catastrophic mandated preventable harm.**

US COVID+ Deaths by Age (CDC Data Jun 25, 2022)

Total 1,006,212 COVID+ Deaths
75% 65+ 51% 75+ 26% 85+
~31% from long term care facilities

Hospitalizations:
91.2% of adults hospitlaized for COVID
had ≥1 underlying medical conditions
65+ yo COVID+ hospitaliztions out number all other age groups combined
SARS-CoV2 IFR for 65+ yo =3.8%
33% 65+ yo infected by seroprevalence data

For <18 yo:
0.106% (1063) of total COVID+ deaths
2666 deaths attributed to pneumonia, influenza, or COVID
(1063 of total 2666, or 40%, respiratory deaths are COVID)
SARS-CoV2 IFR for 0-17 yo 0.0018%
75% 0-17 yo infected by seroprevalence data

For < 25 yo:
0.34% (3421) of total COVID+ deaths
NO excess deaths in 2020 or 2021 for 0-24 yo compared to prior years